

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA**
Richmond Division

LISA SYKES and SETH SYKES,
Individually and as Parents and Natural
Guardians of **WESLEY ALEXANDER**
SYKES, a minor child,

Plaintiffs,

v.

Case No. 3:07CV660

BAYER CORPORATION, aka
BAYER CORPORATION, INC.,
BAYER BIOLOGICAL PRODUCTS,
BAYER HEALTHCARE CORPORATION, INC.,
BAYER PHARMACEUTICALS CORPORATION,
BAYER PHARMACEUTICALS CORPORATION, INC.
Individually and as
Successor-In-Interest to Miles, Inc.

Defendant.

AMENDED COMPLAINT
Personal Injury Action (28 U.S. C. §1332)

The Plaintiffs, Lisa and Seth Sykes, Individually and as Parents and Natural Guardians of
Minor Child Wesley Sykes, by and through undersigned counsel, complaining of the Defendants,
allege as follows:

SUMMARY OF ALLEGATIONS

1. Since approximately 1978, Defendant Bayer Corporation, its licensees, affiliates, subsidiaries and their distributors, have engaged in the sale and distribution of HypRho-D[®] to hundreds of thousands of Rh-negative mothers and their unborn children in order to prevent an uncommon condition of blood incompatibility between some pregnant women and their unborn children.

2. HypRho-D[®] is an Rh-immune globulin product, which nominally contained 0.01% Thimerosal (100 micrograms (mcg) per milliliter (ml)), a preservative, and almost fifty percent (50%) organic mercury by weight. With an average fill volume of 0.7 ml, a nominal dose of HypRho-D[®] would have contained 35 micrograms of organic mercury. Organic mercury is a highly poisonous neurotoxicant, *especially to unborn children*. HypRho-D[®] was typically administered via injections in the arm or hip of the mother of a fetus at 28 weeks gestation when the average fetal weight is approximately three pounds (1.36 kilograms [kg]). Thus, Rh-negative women and their extremely vulnerable unborn children were unknowingly exposed to a highly poisonous chemical substance *two hundred fifty seven (257) times beyond the applicable federal safety limit threshold during the administration of prenatal HypRho-D[®] injections*. Defendant designed, tested (or failed to test), manufactured, promoted, marketed, warranted, sold and distributed HypRho-D[®] without any apparent regard for the poisonous effects of mercury to the children whose mothers received the injection. Finally, in 1996, the Defendant quietly discontinued the use of the mercury-laden Thimerosal preservative in HypRho-D[®] by revamping the formula and changed the name of the product to BayRho-D.

3. Upon information and belief, Plaintiff, Minor Child Wesley Sykes, developed severe neurodevelopmental disorders associated with high mercury exposure levels as a result of HypRho-D[®] exposure in utero, and as a result he has suffered serious permanent injury.

PARTIES AND JURISDICTION

4. Plaintiffs, Lisa and Seth Sykes, are the natural parents and guardians of Plaintiff, Minor Child Wesley Sykes, and at all times relevant were citizens and residents of Richmond, Virginia.

5. Defendant, **Bayer Corporation, Inc., Individually and as Successor-in-Interest to Miles, Inc.**, hereinafter referred to as Bayer, is an Indiana corporation doing business in the State of Virginia. Plaintiffs are further informed and believe that at all times relevant, Defendant Bayer designed, developed, manufactured, tested (or failed to test), labeled, promoted, marketed, distributed, sold, and warranted HypRho-D[®] containing mercury (Thimerosal) in this state and interstate commerce.¹

6. Upon information and belief, HypRho-D[®] was originally designed, developed, manufactured and sold by Cutter Laboratories. Cutter was acquired by Bayer in 1974. In 1978, Bayer purchased Miles, Inc. Cutter formerly merged into Miles, Inc. in 1993 under the Bayer corporate umbrella and Miles was renamed Bayer Corporation.

¹ Counsel has recently been informed that Bayer Corporation was recently acquired by Bayer Healthcare Corporation, Inc., a Delaware corporation with its principal place of business in New Jersey, but without any responses to discovery having been received to date, this information cannot be confirmed.

7. **Bayer Biological Products** is a division of Bayer Corporation. Upon information and belief, Defendant Bayer Biological Products is the division of Bayer responsible for the manufacture, sale and distribution of Bayer's immune globulin products. Upon information and belief, the worldwide headquarters of Bayer Biological Products is located in Research Triangle Park, Durham County, North Carolina.

8. This Court has jurisdiction over this cause of action and personal jurisdiction over the defendants under VA Code § 8.01-328.1.

9. Venue for this case is proper pursuant to VA Code § 8.01-261.

FACTUAL ALLEGATIONS

10. Mercury is one of the most toxic substances on earth.² The correlation between mercury exposure and neurological damage *even at relatively low doses especially in prenatal exposure* is well established in scientific and medical literature.³ Fetuses and newborns are highly susceptible to mercury's effect as it interferes with the developmental processes of the infant brain. Organic mercury readily crosses the placenta and blood-brain barrier.

11. The symptoms of mercury poisoning have been recognized since the Eighteenth century. Symptoms of mercury poisoning include paresthesias, ataxia, and impairments of speech, hearing, and vision. In children exposed during fetal development, severe neurological

² Instances of mercury poisoning have been reported since Roman times.

³ Mercury deposits can be found in all body tissue and its effects can involve multiple organ systems. Developing fetuses and infants are more susceptible to mercury's effect as it interfered with the developmental process of the brain and central nervous system and impairs digestive function of the body.

dysfunctions and developmental abnormalities, including mental retardation, cerebral palsy, deafness, and blindness have been reported.⁴

12. The medical and scientific literature contains many reports of injury to human beings as a result of exposure to mercury. As a result, over the years, many uses of mercury have been discontinued due to concerns of mercury poisoning in humans associated with the use of these products.

13. Thimerosal is an organic mercury antiseptic compound, almost fifty percent (50%) organic mercury by weight, used as a preservative in pharmaceutical preparations.

14. Thimerosal was used as a preservative in HypRho-D[®], an Rh- immune globulin product provided to pregnant women with an uncommon blood incompatibility with their unborn children. HypRho-D[®] is typically injected into a pregnant woman at 28 weeks gestation, when the fetus weighs approximately 3 pounds.

15. A single dose of HypRho-D[®] is generally 0.7 ml and nominally contained 100 mcg of Thimerosal per milliliter. Thus, a single dose of HypRho-D[®] nominally contained approximately 35 mcg of organic mercury.

16. At the time of the injury, the applicable Environmental Protection Agency (EPA) safety standard for mercury exposure was (and currently is for both the EPA and the Food and Drug Administration [FDA]) 0.1 mcg per kg of body weight per day. The average weight of a fetus at 28 weeks gestation is three pounds or 1.36 kg. *Thus, on average, the unborn HypRho-D[®] recipient received mercury at a level nominally two hundred fifty seven (257) times in excess of applicable EPA and current EPA and FDA safety threshold limit.*

⁴ *Immunization Safety Review: Thimerosal-containing Vaccines and Neurodevelopmental Outcomes*, Institute of Medicine (2001) p. 44.

17. As a result of a HypRho-D[®] injection in the mother at approximately 28 weeks gestation, a highly toxic amount of mercury, as much as two hundred fifty seven (257) times in excess of the EPA and current guideline, was rapidly transported into the bloodstream of the developing fetus, crossing the blood brain barrier into the brain and migrating to organs and tissue. Upon information and belief, the placenta actually pumps the mercury into the fetal capillaries. Thus, throughout the pregnancy, the mercury concentration in the fetus can rise to a much higher level than that in the mother.

18. Upon information and belief, a developing fetus is 5 to 10 times or more sensitive to toxic insult than an adult as a result of underdeveloped body mechanisms, which do not protect the brain and brain systems.

19. As a result, mercury that migrates to the brain, organs and tissue, stays in the body and is not excreted. Upon information and belief, mercury exposure during this stage of life can cause severe neurodevelopmental disorders.

20. Defendants are responsible for the design, manufacturing, promotion, sale and/or distribution of Thimerosal-containing HypRho-D[®] routinely administered to Rh-negative mothers and their unborn and newborn children.

21. HypRho-D[®] was promoted by the Defendants at all relevant times without any reference to the toxic hazards and potential public health ramifications resulting therefrom.

22. Upon information and belief, in 1996, Defendant Bayer quietly discontinued the use of Thimerosal in HypRho-D[®] by reformulating the design and issued a new Thimerosal-free product, BayRho-D[®], in the midst of growing concern of the association of neurodevelopmental disorders in children exposed to mercury products.

23. On or about December 16, 1994, Plaintiff, Minor Child Wesley Sykes, at approximately 28 weeks gestation, was exposed to highly toxic organic mercury through a HypRho-D[®] product injected into his mother.

24. Upon information and belief, said HypRho-D[®] product injected into Lisa Sykes can be identified as HypRho-D[®].

25. Upon information and belief, said HypRho-D[®] product, contained Thimerosal and was manufactured by Defendant Bayer.

26. Upon information and belief, at all times relevant, Defendant Bayer had actual knowledge that HypRho-D[®] products would be injected into the mothers of developing fetuses, that said products had never been subjected to safety and efficacy studies, and that said products contained a known neurotoxin, namely mercury.

27. Defendant Bayer added Thimerosal to HypRho-D[®] without regard for the impact of mercury on fetuses and infants, with full knowledge that single dose injectibles such as this could be manufactured without any preservative or with other safer preservatives.

28. Prior to and during the period that the Defendant Bayer added Thimerosal to HypRho-D[®], Defendants knew or should have known that mercury is a bioaccumulative neurotoxicant and is highly toxic to the human system, particularly to the vulnerable, developing systems of fetuses and newborns.

29. The Defendant continued to promote the use, sale and distribution of Thimerosal and/or Thimerosal-containing HypRho-D[®] despite growing concern in the scientific and medical professions for the association of neurodevelopmental disorders and mercury poisoning in children exposed to mercury containing products, knowing full well that their design was

defective and could easily be changed to a product that contained no preservative or a safer preservative that is not a bioaccumulative neurotoxin.

30. As a direct and proximate result of the mercury in HypRho-D[®] to which minor child Plaintiff was exposed he suffers from neurological damage. He has sustained mental, developmental and neurological incapacity and associated learning disabilities. He has required, and will continue to require, intense medical treatment and continual psychological, educational, occupational, rehabilitative and dietary therapies. Minor Child Plaintiff has suffered reduced earnings capacity, loss of enjoyment of life and loss of economic opportunity. His permanent injuries encompass medical, mental and social damage disabling him from the usual and customary activities of a child his age and of those which children can normally experience and enjoy in their lifetime. Due to the constant care required by their child, Lisa and Seth Sykes have incurred medical expenses, have rendered, and will continue to render, nursing care and have suffered emotional distress and loss of opportunities.

COUNT ONE: NEGLIGENCE (DESIGN DEFECT)

31. Plaintiffs incorporate by reference the earlier paragraphs of this Complaint.

32. At all material times, Defendant Bayer had a duty to use ordinary care to design a product that would be reasonably safe for its intended purpose and for any other reasonably foreseeable purpose. Upon information and belief, Defendant Bayer failed to perform this duty. Bayer's negligence included, but is not limited to, the following:

- a. Bayer failed to properly design a product that was safe for developing fetuses;
- b. Failed to design a product that was free of highly toxic mercury, by either petitioning the FDA to allow them to produce a "preservative-free" product (as

was done by another manufacturer) or by using a safer preservative (such as 2-phenoxyethanol, which was available at the relevant times) ;

- c. Bayer failed to ever “redesign” their product until after it was injected into the mother of Wesley Sykes as described above, despite the fact that they knew or should have known that their product was unsafe, and despite the fact that they knew or should have known that their product could be made mercury-free by using an alternative preservative or no preservative at all;
- d. Bayer’s improper design of HypRho-D[®] resulted in a product that was adulterated in violation of federal law, including 21 U.S.C. 351 (a)(2)(B), never demonstrated to be sufficiently non-toxic under 21 C.F.R. 610.15(a), which is specifically required for biological drug products in accordance with 42 U.S.C. Sec. 262(a)(2)(C)(i)(I); and
- e. Bayer failed to use ordinary care to design this product in any other respects which shall be determined through discovery and proven in the trial of this action.

33. Defendant Bayer knew or should have known that the aforementioned HypRho-D[®] was not safe and could cause serious side effects of which consumers and their medical care providers would not be aware.

34. Defendants Bayer and Bayer Biological Products knew or should have known that HypRho-D[®] would cause serious injury, including mercury poisoning, to persons such as the Plaintiffs, and that the reasonable, foreseeable and intended use of its product could and would cause significant injury.

35. As a direct and proximate result of the conduct of the Defendant Bayer as described above, the minor Plaintiff has sustained mental, intellectual, developmental and neurological

incapacity and associated learning disabilities, affect disorders and impairments, and resultant health care expenses, reduced earnings capacity, loss of enjoyment of life, loss of economic opportunity, permanent disability, and other injuries entitling the Plaintiffs to receive compensatory damages in an amount to be determined by a jury in the trial of this action, but in any event, in excess of the sum of Ten Thousand Dollars (\$10,000.00).

COUNT TWO: BREACH OF WARRANTIES

36. Plaintiffs incorporate by reference the earlier paragraphs of this Complaint.

37. The Defendant, by and through the sale of the product in question, expressly and impliedly warranted to the public generally, and to the Plaintiffs and their providers specifically, that HypRho-D[®] was of merchantable quality and was safe and fit for the use for which it was intended.

38. Plaintiffs and their providers made use of the product as alleged herein, and reasonably relied upon the skill and judgment of the Defendant as to whether the product was of merchantable quality and safe and fit for its intended use, and Plaintiffs relied on the express and implied warranties of the Defendant. Contrary thereto, HypRho-D[®] was not of merchantable quality and was not safe nor fit for the use for which it was intended, and in fact had serious life threatening side effects.

39. Defendant breached the express and implied warranties, all as alleged above.

40. Defendant's breach of these warranties was a direct and proximate cause of Plaintiffs' injuries as described above.

DEMAND FOR JURY TRIAL

THE PLAINTIFFS DEMAND A JURY TRIAL ON ALL ISSUES OF FACT SO TRIABLE.

WHEREFORE, the Plaintiffs, Individually and in their representative capacity as Guardians ad Litem of Minor Child Wesley Sykes, respectfully request that that they have and recover of the Defendants, jointly or severally, as follows:

1. Compensatory, consequential and punitive damages in an amount to be determined by a jury in the trial of this action, but in any event, in excess of the sum of Ten Thousand Dollars (\$10,000.00);
2. The costs of this action, including reasonable attorney fees and interest as provided by law, and as this honorable court deem just and proper;
3. For such other and further relief as this Honorable Court may deem just and proper as to each count alleged in this complaint.

Respectfully submitted
this 22nd day of January, 2008.

LISA SYKES, et al.

/s/Clifford J. Shoemaker
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CERTIFICATE OF SERVICE

I herby certify that on the 22nd day of January, 2008, I will electronically file the foregoing with the Clerk of Court using the *CMIECF* system, which will then send notification of such filing to the following:

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